(12) UK Patent Application (19) GB (11) 2 183 483 (13) A

(43) Application published **10 Jun 1987**

(21) Application No **8627773**

(22) Date of filing **20 Nov 1986**

(30) Priority data

(31) **8528590** (32) **20 Nov 1985** (33) **GB**

(51) INT CL[4]
A61F 5/34

(52) Domestic classification (Edition I)
A5R EY
A4M 1B8 1B9 1BX

(56) Documents cited
None

(58) Field of search
A5R
A4M
Selected US specifications from IPC sub-class A61F

(71) Applicant
Smith and Nephew Associated Companies plc

(Incorporated in United Kingdom),

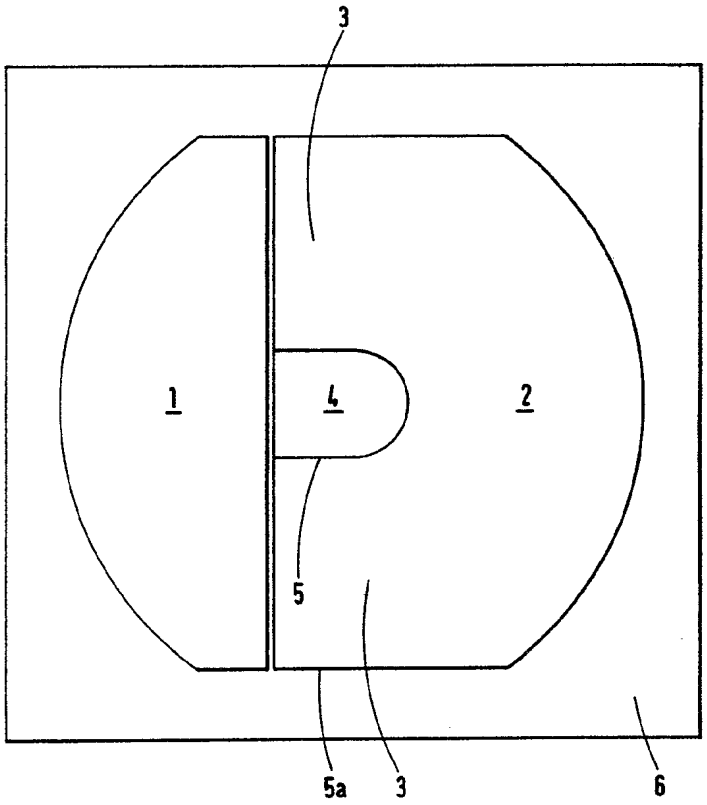
2 Temple Place, Victoria Embankment, London WC2R 3BP

(72) Inventor
Patrick Lewis Blott

(74) Agent and/or Address for Service
Dr. W. G. Cole, Smith & Nephew Research Ltd., Gilston Park, Harlow, Essex CM20 2RQ

(54) **Pressure sore device**

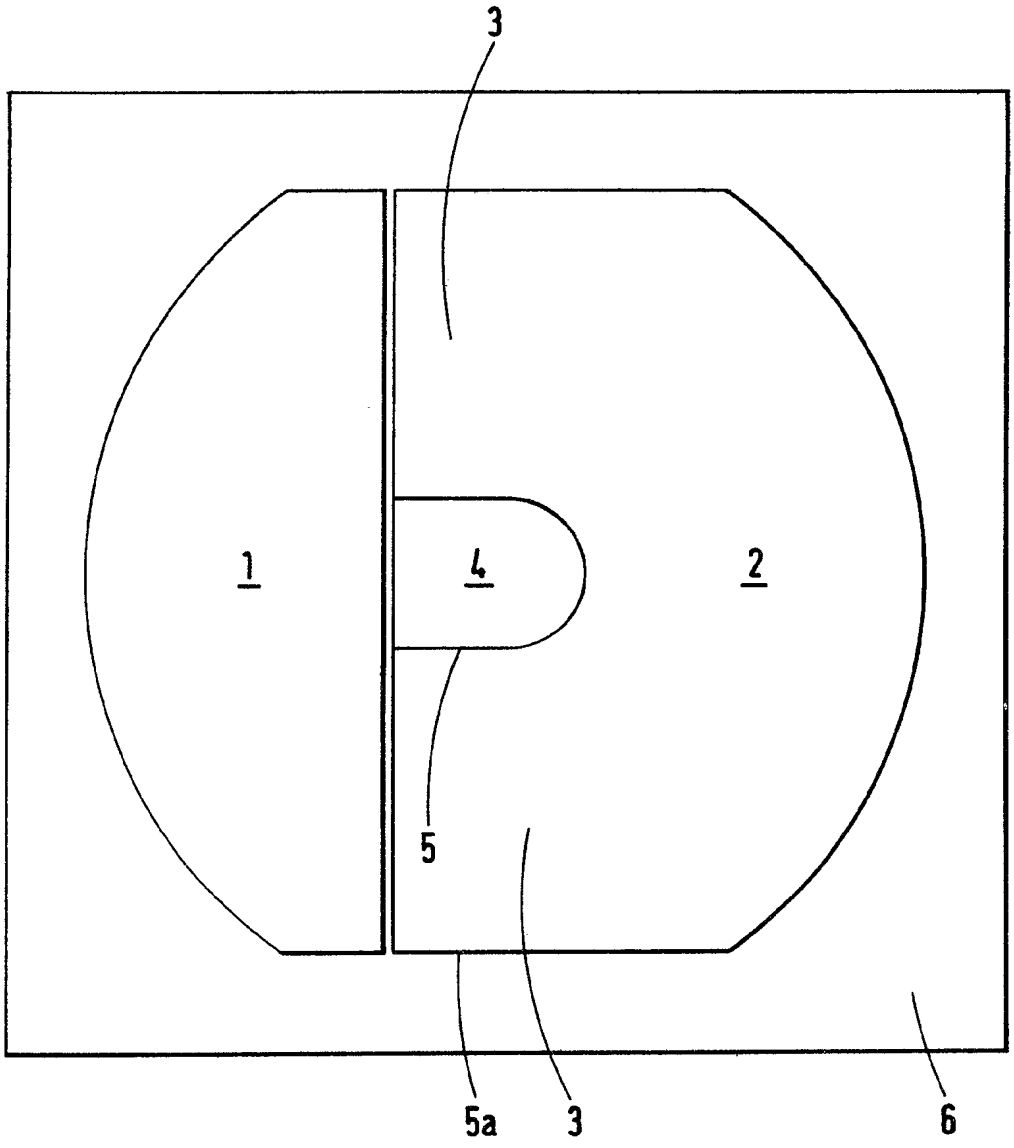
(57) A device for the prophylaxis of pressure sores associated with the trochanter is described. The device comprises two flexible elastomeric compartments which contain a liquid and which are attached to a body contacting film. The volume of the first compartment is from 80 to 180 ml and is preferably in the shape of a segment of a circle, the volume of the second compartment is from 80 to 160 ml and is preferably U-shaped. By arranging the open end of the U-shape compartment to be adjacent to the straight portion of the segment-shaped compartment, the device is effective in spreading the pressure of a patient lying on the device evenly over the trochanter and the surrounding area and also reducing the overall pressure.



GB 2 183 483 A

The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

2183483



SPECIFICATION

Pressure Sore Device

The present invention relates to devices for application to the pressure bearing surfaces of, for example bedridden patients, for the prophylaxis of pressure sores. In particular it relates to specially shaped devices which comprise a liquid retained with flexible elastomeric envelopes; to methods of forming such devices and to their use.

The devices of the present invention are particularly useful in preventing pressure sores associated with the trochanter, that is in the area of the hip. The pressure on the trochanter of a subject lying on their side is considerably higher than the pressure found in a bedridden patient when measured at the heel or the sacrum.

The nature of this site is such that the area over which the pressure is manifest is small and it has proved difficult to transfer the pressure away from the site without a deleterious increase in pressure in a nearby area. Thus instead of attempting to reduce the pressure as in the case in heel or sacrum devices the main aim of the present device is to spread the pressure evenly over the trochanter and surrounding area and the subsidiary aim is to make this pressure as low as possible.

I have found that a device comprising two compartments of a specified range of volumes and shape will provide prophylaxis for pressure sores in the region of the trochanter by spreading the pressure evenly over the trochanter and the surrounding area and also reducing the overall pressure.

Accordingly the present invention provides a device for the prophylaxis of pressure sores which device comprises two flexible elastomeric compartments retaining therein liquid which compartments are attached to a body contacting film characterised in that the volume of the first compartment is between 80 and 180 ml and the volume of the second compartment is between 80 and 160 ml.

Suitably the first compartment will have a volume of from 80 to 180 ml, more suitably from 85 to 140 ml and preferably from 90 to 120 ml, for example 90 ml, 100 ml and 120 ml.

Accordingly the present invention provides a device for the prophylaxis of pressure sores which comprises two flexible elastomeric compartments retaining therein a liquid which compartments are attached to a body contacting film having a moisture vapour transmission rate of greater than 300 gm^{-2} 24 hr^{-1} at 37°C at 100% to 10% relative humidity difference and liquid is viscous and absorbs moisture vapour characterised in that the volume of the first compartment is between 80 and 180 ml and the volume of the second compartment is between 80 and 160 ml.

Aptly the first compartment will be in the shape of a semi circle or approximately so, that is the compartment may form the segment of a circle. Suitably the radius of the circle of which the first compartment forms part is from 8.0 to 12.0 cm, more suitably 9.0 to 11.0 cm and preferably from 9.5 to 10.5 cm for example 9.5 cm, 10 cm. Suitably the shape is on the form of a segment of a circle in which the straight part of the segment has a length of from 14.0 to 18 cm more suitably 14.5 to 15.0 cm and preferably 15.0 to 16.0 cm.

Suitably the second compartment will have a volume of from 80 to 160 ml, more suitably from 90 to 140 ml and preferably from 100 to 120 ml, for example 100 ml, 110 ml and 120 ml.

Aptly the second compartment will be 'U'-shaped. Though described as U-shaped, this description shall also include flexible elastomeric envelopes, in the shape of a letter 'C', a horse shoe and flexible elastomeric envelopes in the shape of an interrupted circle, that is essentially 'U'-shaped.

Suitably the second compartment is a flexible elastomeric envelope in the shape of a letter 'U' which is suitably between 8 and 20 cm long and preferably 10 to 16 cm long, when measured from the ends of the "arms" to the "base' of the U-shape. Suitably the second compartment is 8 to 20 cm wide and is preferably 12 to 16 cm wide when measured between the outer faces of the two 'arms' of the U-shape compartment. Each arm of the second compartment is suitably between 1 cm and 10 cm wide and preferably 2 to 6 cm wide when measured between the outer and inner face of each arm. The two arms of the second compartment are separated by a gap which has a width of between 1 cm and 10 cm and preferably a width of between 2 cm and 6 cm.

The two compartments are aptly arranged so that the open end of the 'U' shaped compartment is adjacent to the straight portion of the semicircularly shaped first component.

Each of the compartments is filled with a viscous moisture absorbing fluid as hereinafter described, and will be filled to give a thickness of between 0.5 and 3 cm and preferably between 1 and 2 cm to each compartment.

When reference is made to moisture vapour transmission rate, it is intended that such measurements are carried out by the Payne Cup method which is described in the Description.

Suitable examples for the film which contacts the body of the wearer of the device are described in British Patent specification No. 1280631 as backing materials, which are incorporated herein by cross-reference. Suitable polymers for forming the film are polyurethanes such as those known as Estane (Registered Trade Mark of B. F. Goodrich Ltd.). Suitable Estanes include Estane 5702, 5701, 5714F and 580201.

Preferred polymers, however, for forming the film are polyetherester block copolymers such as Hytrel (Registered trade mark). Suitable Hytrels include Hytrel 4056. Yet other preferred polymers for forming the film are polyether polyamide block copolymers such as Pebax (Registered trade mark). Suitable Pebax include Pebax 2533 SN 00.

The thickness of the film employed in the device of this invention is chosen to produce the desired moisture vapour transmission rate (MVTR). Suitably the thickness of the film which will give the correct MVTR and be sufficiently strong to withstand the

pressure applied to it will be in the range 25 to 100 microns. The film will be chosen so that its MVTR will be greater than 300 gm^{-2} 24 hr^{-1} and preferably will be greater than 500 gm^{-2} 24 hr^{-1}, at 37°C and at 100%—10% relative humidity.

For ease of manufacture it is convenient to form the two compartments entirely of a moisture vapour permeable film. However, it is envisaged that the moisture absorbing viscous liquid may be retained between a moisture vapour permeable film which is to contact the skin of the wearer and a moisture impermeable film or a less permeable film. The moisture vapour impermeable film may be polyolefin, polyvinylchloride or the like.

In a second and preferred aspect of the invention the surface of the device which is to contact the skin will carry an adhesive layer whereby the device may be adhered to the skin in use. By adhering the device to the skin it is less likely to be dislodged or moved out of place if the wearer moves or is moved or if the moisture absorbing viscous liquid is relatively stiff. Suitable adhesives must be compatible with the skin, that is they will be hypoallergenic. Favoured adhesives may be synthetic polymers or mixtures thereof. Such adhesives may be selected from those described in British Patent Specification No. 1280631 and European Patent Application No. 35399, both of which are incorporated herein by cross-reference. Preferred adhesives are those which have a MVTR such that the adhesive together with the film which is in contact with the skin has a MVTR of greater than 300 gm^{-2} 24 hr^{-1} when measured at 30°C and 100%—10% relative humidity. Suitable adhesives are those formed from polyacrylates or polyvinyl ethers.

Normally the adhesive will be applied to the film in the form of a continuous layer. However it is envisaged that the adhesive could be applied to form a discontinuous or a pattern spread layer. If desired the adhesive may incorporate an antibacterial agent such as chlorhexidine salt.

In a further and much preferred aspect the film which forms the body contacting layer may be extended to form a margin around the moisture absorbing viscous liquid filled compartments. The body contacting layer may carry an adhesive layer for sticking to the skin over the whole of its surface or only on the marginal portions. The adhesive layer may be continuous or discontinuous or a pattern spread layer. It is preferred that the adhesive is continuous and is present only on the extended margin of the device.

It is envisaged that once applied to the body the device can remain in position for a week or even longer. During this period the moisture produced by normal perspiration of the skin under the device must be removed otherwise the skin will become waterlogged and degenerate. Thus the moisture must be transmitted through the walls of the compartments and absorbed by the moisture absorbing viscous liquid.

Suitably the moisture absorbing viscous liquid will be a material which is a viscous liquid and which will absorb moisture vapour. Suitable materials which are moisture absorbing viscous liquids include polyurethanes, polyethylene glycols, propylene glycols, polyoxyethylene polyoxypropylene diol block copolymers which have the correct viscosity characteristics and are capable of deforming so as to distribute an applied pressure more or less evenly over their surface. Suitable polyurethane moisture absorbing viscous liquids include those hydrophilic polyurethane gels described in International Application No. WO 82/01306 and European Patent Application No. 122035 which are incorporated hereinafter by cross reference.

It is also envisaged that the moisture absorbing viscous liquid could comprise a viscous liquid which contained a hygroscopic material.

Suitable viscous liquids include those moisture absorbing viscous liquids listed above.

Other suitable viscous liquids include those made by materials such as polyvinyl alcohol, polyvinyl pyrrolidone, polyacrylamide, polyethylene glycol, carboxymethylcellulose, cellulose and cellulosic derivatives, vegetable gums such as guar gum, gum agar which when added to a suitable liquid such as water cause that liquid to become viscous. A preferred viscous liquid is an aqueous solution of a polymeric material such as polyvinyl alcohol and polyvinyl pyrrolidone.

Suitable hygroscopic materials for which may be included in the viscous liquid include inorganic materials such as anhydrous silica gel, anhydrous aluminium oxide and sodium bromide. Other suitable hygroscopic materials include organic compounds such as glycerol, glycerine and propylene glycol.

Suitably the viscosity (as measured at 39°C using a Ferranti Shirley Cone and Plate Viscometer with a 1 cm radius cone and a 1200 g spring) of the moisture absorbing viscous liquid will be between 500 and 25,000 Poise and preferably between 1,500 and 6,000 Poise.

The moisture absorbing viscous liquid when contained in a device will suitably absorb moisture vapour at a rate greater than 50 mg/72 hrs/cm^2 of the skin contacting surface of a device and will preferably absorb moisture vapour at a rate greater than 150 mg/72 hrs/cm^2 of the skin contacting surface of a device.

The moisture absorbing viscous liquid and film forming the walls of the compartments and the adhesive when present are suitably all transparent so that the condition of the skin beneath the device may be monitored during the wearing period.

The flexible elastomeric compartments may be made from the appropriate film by casting or extruding the film as a sheet and then vacuum moulding to provide a first film of the appropriate thickness and three dimensional shape. A second film is heat sealed to the first film and the appropriate volume of moisture absorbing viscous liquid is placed in each compartment and the compartments finally sealed around the viscous liquid so that there is suitably no air left within the device.

Preferred embodiments of devices of the present invention will now be described by way of example

only and with reference to the accompanying drawing in which:—

Figure 1 shows a top view of a device suitably for application to the trochanter of a patient.

Figure 1 shows a device with two compartments which is suitable for use on and around the trochanter of a patient. The first compartment (1) is in the form of a segment of a circle. The radius of the circle is 9.5 cm with the short side pieces 2.0 cm and the chord of the circle 15.0 cm. The second compartment (2) is in the form of a letter 'U'. The two arms (3) the compartment are separated by a gap (4) which is 2 cm. The width of each arm from the outer face (5) to the inner face (6) of the arm is 6.5 cm. The width of the base is 15 cm. The two compartments are filled with a moisture absorbing viscous liquid to a thickness of 1 cm. The walls of the compartments are formed from a moisture vapour permeable polyurethane which is approximately 75 µm. The two compartments are surrounded by an extended area (6) which is formed from a moisture vapour permeable polyurethane and coated on one side with an adhesive. The internal piece of the 'U' shape fits over the trochanter with the front bag comprising the first compartment and the back bag comprising the 'U' shaped second compartment. The device of the above size typically contains 90 ml in the front bag and 120 ml in the back bag.

Description

Determination of Moisture Vapour Transmission Rates

Discs of the material under test are clamped over Payne Permeability Cups (flanged metal cups) using sealing rings and screw clamps. The exposed surface area of the test sample is 10 cm^2. Each cup contains approximately 10 ml of distilled water.

After weighing the cups are placed in a fan assisted electric oven which is maintained at 37±−1°C. The relative humidity within the oven is maintained at approximately 10% by placing 1 kg of anhydrous 3—8 mesh calcium chloride on the floor of the oven.

The cups are removed after 24 hours, allowed to cool for 20 minutes and reweighed. The moisture vapour transmission rate of the test material is calculated from the weight loss and expressed in units of grams of weight per square metre per 24 hours.

EXAMPLE 1

A Device Suitable for Use on the Trochanter

A polyether polyamide block copolymer film was extruded in a conventional manner using a melt temperature of approximately 185°C. The resultant film thickness was approximately 170 microns. This film was moulded into the appropriate shape using a vacuum mould. The average thickness of the film after vacuum moulding was approximately 75 microns.

The following description of the device is made with reference to figure 1 and the description thereof.

The moisture absorbing viscous liquid was prepared by adding 60 gms of polyvinyl alcohol (m.w. 29,400) grade GL05 and 100 gms sodium bromide to 100 gms of water.

90 mls and 120 mls of the moisture absorbing viscous liquid was then transferred to the two compartments of the device formed from the polyether polyamide film in the vacuum mould. A further piece of extruded polyether polyamide copolymer film with a thickness of 75 microns was then heat sealed to the moisture absorbing viscous liquid filled device in such a manner as to exclude all the air from the envelope thus formed. The polyether polyamide copolymer film thus sealed to the moisture absorbing viscous liquid filled device extended on all sides by 10 cm beyond the moisture absorbing viscous liquid filled envelope. This extended area of polyether polyamide film was coated with a suitable pressure sensitive adhesive at a mass weight of 30 gms. The adhesive face of the device was then placed onto a silicone release paper and the whole device sealed into a substantially vapour impermeable bag for storage.

CLAIMS

1. A device for the prophylaxis of pressure sores which device comprises two flexible elastomeric compartments retaining therein liquid which compartments are attached to a body contacting film characterised in that the volume of the first compartment is between 80 and 180 ml and the volume of the second compartment is between 80 and 160 ml.

2. A device as claimed in claim 1 in which the first compartment is in the shape of a segment of a circle.

3. A device as claimed in either of claims 1 or 2 in which the second compartment is U-shaped.

4. A device as claimed in any one of claims 1 to 3 in which the liquid is viscous and absorbs moisture vapour.

5. A device as claimed in any one of claims 1 to 4 in which the body contacting film has a moisture vapour transmission rate of greater than 300 gm^{-2} 24 h^{-1} at 37°C at 100% to 10% relative humidity difference.

6. A device as claimed in any one of claims 1 to 5 in which the thickness of the filled compartments is between 0.5 and 3.0 mm.

7. A device as claimed in any one of claims 1 to 6 in which the body contacting film carries an adhesive layer whereby the device may be adhered to the skin in use.

8. A device as claimed in any one of claims 4 to 7 in which the liquid within the compartments additionally contains a hygroscopic material.

9. A device as claimed in any one of claims 4 to 8

in which the viscosity of the moisture absorbing viscous liquid is between 500 and 25,000 Poise when measured at 39°C using a Ferranti Shirley Cone and Plate Viscometer with a 1 cm radius cone and a 1200 g spring.

10. A device as claimed in any one of claims 4 to 9 in which the moisture absorbing viscous liquid when contained in a device will suitably absorb moisture vapour at a rate of greater than 50 mg/72 h/ cm^2 of the skin contacting surface.

Printed for Her Majesty's Stationery Office by Courier Press, Leamington Spa, 6/1987. Demand No. 8991685.
Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.